

REMARKS

I. Introductory Remarks

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and following remarks.

It is acknowledged that the amendments are being presented after final rejection of the application; however, entry of the amendments is respectfully requested because Applicants believe that the amendments place the application in condition for allowance, without raising new issues or introducing new subject matter into the application.

Upon entry of the amendments, claims 9, 11-14 and 16-17 will remain pending in this application. Claim 18 has been cancelled, and its limitations have been incorporated into claims 9 and 13. Claims 9 and 13 also have been amended to further define heavy chain variable region framework sequences for the humanized PM-1 antibody. Support for these further amendments exists in Table 3 of WO 92/19759, which the specification incorporates by reference at the paragraph bridging pages 10-11.

In connection with the amendment of claims 9 and 13, applicants also have amended the paragraph that bridges pages 10-11 of the specification to explicitly describe heavy chain variable region framework sequences for the humanized PM-1 antibody. Again, this description previously was incorporated by reference to WO 92/19759.

None of the amendments add new matter into the application, for reasons explained below.

II. Incorporation of WO 92/19759 by Reference

The Office objected to the specification, alleging that the incorporation of WO 92/19759 by reference is improper for three reasons. First, the Office alleged that the application merely references WO 92/19759, and that such reference is insufficient. Second, the Office alleged that the specification does not adequately identify the portions of WO 92/19759 to be incorporated. Third, the Office alleged that incorporation of WO 92/19759 by reference would require submission of a certified translation of that document. Applicants respectfully traverse these allegations.

It is true that “mere reference to another [document] is not an incorporation of anything therein into the application,” but this application goes beyond merely referencing WO 92/19759. The application cites WO 92/19759 for description of a preferred embodiment – the reshaped human antibody hPM-1. In relevant part, the application read as follows when it was filed:

One of the known methods may be used to obtain a reshaped human antibody which is useful according to the invention. A preferred example of such a reshaped human antibody is hPM-1 (see Intl. Unexamined Patent Application No. WO92-19759).

Page 10, line 35 – page 11, line 2. This constitutes more than a mere reference to other art. It is a clear indication that hPM-1, as described in WO 92/19759, constitutes part of the present invention.

Case law supports the incorporation of WO 92/19759 into this application. For example, in *In re Fouche*, 439 F.2d 1237, 1238, 120 (CCPA 1971), the court found a teaching that “the compound can be ‘prepared as described in Example 1 of our application No. _____’” was sufficient to effect incorporation by reference of the related application, even though no identifying information was provided when the host application was filed. According to *Fouche* and other cases, a teaching indicating that certain information is disclosed in another document will effect an incorporation by reference of that information. See, e.g., *In re Voss*, 557 F.2d 812, 816 (A statement that “[r]eference is made to [U.S.] Patent No. 2,921,971 for a general discussion of glass-ceramic materials and their production” effected an incorporation by reference of that patent); *In re Ziegler*, 363 F.2d 888, 890-92 (CCPA 1966) (A discussion of catalytic processes disclosed in prior applications effected incorporation by reference of catalysts disclosed in the prior applications); *In re Fried*, 268 F.2d 223, 224 (CCPA 1959) (A teaching that a method step can be accomplished “as in” a cited patent effected incorporation by reference of the method disclosed in the cited patent). Thus, the law is generous in finding incorporation by reference. This reflects a clear policy favoring incorporation by reference, because the practice promotes “economy, amplification, [and] clarity of exposition.” *In re Seversky*, 474 F.2d 671, 674 (CCPA 1973).

Not only does the application clearly indicate that subject matter in WO 92/19759 constitutes a part of the invention, but the application also sufficiently identifies the relevant portions of WO 92/19759. The application references WO 92/19759 for disclosure of hPM-1, or humanized PM-1, antibody. This is a major aspect of WO 92/19759, and humanized

PM-1 antibody is described throughout that document. See, e.g., col. 2, ll. 45-54; col. 3, ll. 29-41; col. 8, ln. 63 – col. 21, ln. 42; col. 22, ln. 34 – col. 23, ln. 43; Examples 7-17; claim 3 and claim 6 of U.S. Patent 5,795,965, which issued from the U.S. national stage of WO 92/19759. Because essentially the entire disclosure of WO 92/19759 relates to humanized PM-1 antibody, the entire document is properly incorporated by reference. See, e.g., *Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc.*, 127 F.3d 1065, 1069 (Fed. Cir. 1997) (A general incorporation by reference made in the context of a preferred embodiment effected incorporation of the entire document into the host patent.)

Lastly, the Office indicated that a certified translation of WO 92/19759 is required. A certified translation of WO 92/19759 previously was submitted to the Office in conjunction with the U.S. national phase examination of that application, which issued as U.S. Patent 5,795,965. The attached *Notification of Acceptance of Application under 35 U.S.C. 371 and 37 CFR 1.494 or 1.495* evidences that the Office received that translation. Therefore, Applicants respectfully request that the Office refer to the '965 patent or, if necessary, to the certified translation of WO 92/19759 already on file.

III. Definiteness of Claims 9, 11-14 and 16-18

Claims 9, 11-14 and 16-18 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for referring to “humanized PM-1 antibody.” According to the Office, the laboratory designation “humanized PM-1 antibody” is vague and indefinite because laboratory designations cannot be held constant outside of the laboratory in which they are used.

The foregoing claim amendments obviate this rejection. Without acquiescing to the rejection’s propriety, Applicants have further defined the humanized PM-1 antibody by reference to framework and CDR amino acid sequences. Accordingly, Applicants respectfully request withdrawal of the rejection.

IV. Written Description Support for Claim 18

Claim 18 was rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not provide support for a humanized PM-1 antibody comprising the sequences of SEQ ID NOS: 2-16, as set forth in the claim. Applicants respectfully traverse this rejection.

Although claim 18 is presently cancelled, the rejection relates to the incorporation of WO 92/19759 by reference. As explained in detail above, the incorporation is proper. For all of the previously stated reasons, this application contains a written support of the humanized PM-1 antibody as set forth in the claims. Accordingly, Applicants request withdrawal of the rejection.

V. Concluding Remarks

The application is in condition for allowance, and Applicants request favorable reconsideration of it. If the Examiner believes that an interview would advance prosecution of the application, he is invited to contact the undersigned by telephone.

Respectfully submitted,

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